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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,606	03/18/2004	Susan K. Brown-Skrobot	VTN-5054	5871

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EXAMINER

STITZEL, DAVID PAUL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/803,606	Applicant(s) BROWN-SKROBOT ET AL.	
	Examiner David P. Stitzel, Esq.	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>08/29/05</u> . | 6) <input type="checkbox"/> Other: ____ |

OFFICIAL ACTION

Status of Claims

Claims 1-19 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,320,843 (hereinafter the Raheja '843 patent).

With respect to claims 1-3 and 6 of the instant application, the Raheja '843 patent discloses an injection or blow molded antibacterial article for storing a contact lens in an ophthalmic solution, wherein said molded antibacterial article comprises a thermoplastic polyolefin resin, such as polyethylene, polypropylene, or a mixture thereof, having a titanium oxide colorant incorporated therein (column 1; column 2; column 3, lines 21-38; column 4, Example 1 and 2; column 5, Example 2 continued).

2. Claims 1, 10 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by International Application Publication WO 02/44260 (hereinafter the Portnoy '260 publication).

With respect to claims 1, 10 and 11 of the instant application, the Raheja '843 publication discloses an injection molded contact lens casting cup comprising a metallocene catalyzed monomer or copolymer of polypropylene and/or polyethylene, having an additive, such as a colorant or a whitening agent, incorporated therein (page 1, lines 5-8; page 2, lines 29-32; page 4, lines 1-5; page 6, lines 22-28; page 23, lines 1-4).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 4, 5, 7 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of U.S. Pre-Grant Patent Application Publication 2002/0136899 (hereinafter the deRojas '899 publication).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 4, 5, 7 and 8 of the instant application, although the Raheja '843 patent teaches incorporating a titanium oxide colorant into a molded antibacterial article for storing a contact lens in an ophthalmic solution, the Raheja '843 patent does not explicitly teach incorporating a photochromic compound as an opacifying agent into said article. However, the

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deRojas '899 publication teaches coating and spraying a contact lens with a photochromic compound, selected from a spirooxazine, naphthopyran, chromene (a.k.a., benzopyran), spiroindolinonaphthoxazine, or a combination thereof, so as to prevent darkening of the contact lens by imparting protection from ultraviolet radiation ([0015]-[0018], [0020], [0037]-[0039]). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the molded antibacterial article comprising polyethylene and/or polypropylene, of the Raheja '843 patent, by coating and spraying a photochromic compound onto said molded antibacterial article so as to impart protection from ultraviolet radiation and thereby prevent darkening of the contact lens contained therein, as reasonably suggested by the deRojas '899 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to coat and spray a photochromic compound onto said molded antibacterial article so as to impart protection from ultraviolet radiation and thereby prevent darkening of the contact lens contained therein, especially since said molded antibacterial article comprises polyethylene and/or polypropylene, which are transparent thermoplastic polyolefin resins.

2. Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of U.S. Patent 6,054,090 (hereinafter the Duis '090 patent).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claim 9 of the instant application, although the Raheja '843 patent teaches incorporating a titanium oxide colorant or pigment into a molded antibacterial article for storing

a contact lens in an ophthalmic solution, the Raheja '843 patent does not explicitly teach printing an opacifying agent onto a surface of said article. However, the Duis '090 patent teaches a contact lens container having a label printed thereon, wherein said label comprising a dye (column 1, lines 10-21; column 2). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the molded antibacterial article, of the Raheja '843 patent, having a titanium oxide colorant or pigment incorporated therein, by alternatively printing a label comprising a dye, as reasonably suggested by the Duis '090 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to print a label onto said molded antibacterial article so as to provide a label thereon bearing a coating of a desired dye, colorant or pigment.

3. Claims 12 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of U.S. Pre-Grant Patent Application Publication 2002/0046958 (hereinafter the Lipscomb '958 publication).

The teachings of the Raheja '843 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 12 and 13 of the instant application, although the Raheja '843 patent teaches incorporating a titanium oxide colorant or pigment into a molded antibacterial article equipped with a sealable cap for storing a contact lens in an ophthalmic solution, the Raheja '843 patent does not explicitly teach a flexible cover sheet comprising an adhesive laminate of aluminum foil and polypropylene. However, the Lipscomb '958 publication teaches a molded container for storing a silicone hydrogel contact lens comprising polyethylene and/or

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polypropylene, wherein said molded container is equipped with a cover comprising a flexible cover sheet comprising a laminate of a metal foil layer and a heat sealed polyethylene layer (abstract, [0048], [0051]). Although the Lipscomb '958 publication does not explicitly teach polypropylene, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute polypropylene for polyethylene, as said polyolefins are routinely used interchangeably within the art due to their substantially identical chemical properties. It would have been obvious to one of ordinary skill in the art at the time the instant application was filed to modify the sealable cap of the Raheja '843 patent with the flexible cover sheet of the Lipscomb '958 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to utilize a flexible cover sheet with said molded antibacterial article, of the Raheja '843 patent, so as to seal and maintain the ophthalmic solution therein, as reasonably suggested by the Lipscomb '958 publication.

4. Claims 14-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Raheja '843 patent in view of the Lipscomb '958 publication and in further view of U.S. Pre-Grant Patent Application Publication 2003/0044447 (hereinafter the Zanini '447 publication).

The teachings of the Raheja '843 patent and the Lipscomb '958 publication are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 14-19 of the instant application, although the Lipscomb '958 publication teaches incorporating silicone hydrogel contact lenses into the molded container comprising polyethylene and/or polypropylene, wherein said molded container is equipped with

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a cover comprising a flexible cover sheet comprising a laminate of a metal foil layer and a heat sealed polyethylene layer (abstract, [0048], [0051]), the Lipscomb '958 publication does not explicitly teach either a specific species of silicone hydrogel contact lens, or a pharmaceutical agent, incorporated therein. However, the Zanini '447 publication teaches a molded antimicrobial container for storing a silicone hydrogel contact lens comprising transparent polyolefins, such as polyethylene and/or polypropylene; wherein said silicone hydrogel contact lens is formulated from balafilcon A and lotrafilcon A; wherein said antimicrobial component of said molded antimicrobial container is useful for reducing adverse effects associated with microbial production including, but not limited to, ocular inflammation, ocular ulcers, red eye, and microbial keratitis ([0226], [0227], [0228], [0232], [0300]-[0306]). It would have been obvious to one of ordinary skill in the art at the time the instant application was filed to incorporate silicone hydrogel contact lenses into said molded container, as taught by the Lipscomb '958 publication, that are formulated from balafilcon A and lotrafilcon A, as reasonably suggested by the Zanini '447 publication. One of ordinary skill in the art would have been motivated, as well as had a reasonable expectation of success, to incorporate said silicone hydrogel contact lenses formulated from balafilcon A and lotrafilcon A, as taught by the Zanini '447 publication, into the molded antibacterial article comprising a thermoplastic polyolefin resin, such as polyethylene and/or polypropylene of the Raheja '843 patent, as the Zanini '447 publication likewise teaches incorporating said silicone hydrogel contact lenses formulated from balafilcon A and lotrafilcon A into a molded antimicrobial container for storing a silicone hydrogel contact lens comprising transparent polyolefins, such as polyethylene and/or polypropylene.

Conclusion

Claims 1-19 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references.

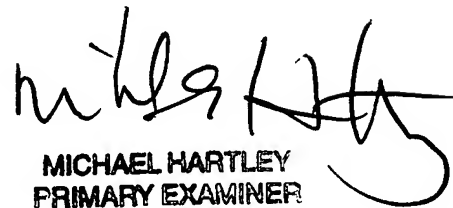
Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.


**MICHAEL HARTLEY
PRIMARY EXAMINER**